Indian pharma cos upbeat on biogenerics

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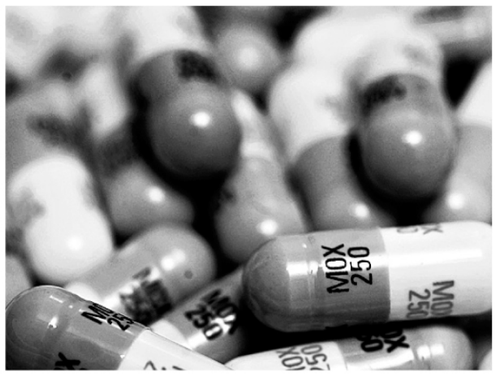

Of the $70 billion global biopharmaceutical segment, $40 billion will go off-patent over the next 5 years

Even as the substitutability of biogeneric or biosimilar medicines with their original patented counterparts continues to be a matter of debate world over, Indian drug companies, which have introduced biogeneric products or copies of biotechnology drugs in the country, are bullish over the marketing prospects of "biogenerics" after patents expire in developed markets. Companies such as Dr Reddy's, Biocon, Reliance Life Sciences and Ranbaxy etc. are all in the process of strengthening their biogeneric portfolio to cater to future global demand.

"The biogeneric market in India is pegged at Rs 600 crore, while the US and EU market for biosimilars is estimated to reach $ 21 billion by 2015", said KV Subramaniam, president and CEO, Reliance Life Sciences (RLS). RLS launched three biosimilars - ReliPoietin (Erythropoietin (EPO), ReliGrast (Granulocyte Colony Stimulating Factor (G-CSF), and ReliFeron (Interferon Alpha 2b) in the domestic market in 2008 and is working on a range of biosimilars, which are at different stages of development viz clinical trials, pre-clinical studies, process development and molecular biology.

"We are concurrently conducting clinical trials for two biosimilars — Erythropoietin and GCSF — in Europe. RLS envisages its subsidiary Reliance GeneMedix Plc as a platform for participating in the European biosimilars market to begin with and eventually for introducing a wide range of biopharmaceuticals. Further, RLS has built significant manufacturing capacity for biopharmaceuticals and all these facilities are compliant with USFDA and EMEA standards," Subramaniam said.

Kiran Mazumdar Shaw, CEO, Biocon shares the enthusiiasm. Of the $70 billion global biopharmaceutical segment, $ 40 billion will genericise over the next 5 years, she said. "EPO, Insulins and Monoclonal Antibodies are the key drivers of this biogeneric opportunity. Indian biopharmaceutical companies like Biocon, Dr Reddy's, Intas and Wockhardt are positioning themselves for this emerging opportunity. Products like Insulin, EPO and GCSF are already there in Latin American, Asian and West Asian markets. All these products are also now being developed for registration in the US and European markets," Shaw added.

While Dr Reddy's has announced generic biopharmaceuticals as an integral part of its mid-to-long term growth strategy, Ranbaxy has laid out its sourcing strategies with smaller biotech firms like Zenotech and Virchow Biotech to ensure supply of biopharmaceuticals.

"We have made significant efforts have over the years succeeded in creating world class infrastructure and a highly capable team. Dr Reddy's has developed and markets two biogenerics , Grafeel (filgrastim) and Reditux (rituximab). Both are sold in markets outside India also. We have a portfolio of nine products in our pipeline with two products at clinical development stage," an official with Dr Reddy's said.

Experts say that Indian companies may not repeat the success they achieved in selling generic medicines in biogenerics. The cost of clinical trials and the absence of substitutability will ensure that only those with deep pockets to launch such products globally will succeed, they feel.

"Two biologicals cannot be compared for efficacy and safety the way two chemical medicines are compared today. Regulators will think twice before allowing a biotech product to be substituted by a low-cost biogeneric. To prove these medicines are safe and effective as medicines, the companies will have to conduct extensive clinical trials," said Shrikumar Suryanarayan, director general, Association of Biotechnology Led Entrepreneurs.

Suryanarayan added that rules governing the marketing of biogenerics in the world's largest drug market – United States –were yet to be framed. Europe and the US are all in the process of finalising their views on biogenerics. The market was there, but it may not be accessible for all Indian biotech firms, he said.

Commenting on Dr Reddy's plans for follow-on biologics, Goldman Sachs Global Investment Research, India Healthcare report, on March 19 ha dcautioned that though Dr Reddy's maintained follow-on biologics as future growth driver and a key opportunity, it "still has a gestation period of around two years before beginning to contribute meaningfully".

"Abbreviated pathways will require an R&D investment of atleast $50 million per biogeneric. Most companies will try and generate atleast part of the clinical data in countries like India to defray costs", said Shaw.

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